K061086

AUG 10 2006

SAFETY & EFFECTIVENESS DATA SUMMARY

Submitters Name, Address & Phone Number:

Nihon Seimitsu Sokki., Co., Ltd.
(Nissei)
2508-13, Nakago,Komochi-Mura
Kitagunma-Gun, Gunma-Ken
377-0293,Japan
+81-0279-20-2311

Submission Correspondent:

Lyle Howard Corporation
106 East 5th Avenue
Mount Dora, FL 32757
USA
Attention: Lynette Howard
908-788-4580

Classification Name: **Noninvasive Blood Pressure Monitor**
Common / Usual Name: **Blood Pressure Monitor**
Proprietary Name: **Model DM-3000 Digital Blood Pressure Monitor**

Establishment Registration Number: 9610827
Classification: Class II, Reg. # 870.1130, DXN, Cardiovascular Devices Panel
Performance Standard: Section 898 and 1010 of the Federal Food, Drug and Cosmetic Act

Substantial Equivalence:

The legally marketed device to which substantial will demonstrated is the Nissei Model DM-3000 Digital Blood Pressure Monitor. This device was cleared for marking under 510(k) No.K993890, SE decision December 3, 1999.

The subject device is essentially an updating of the predicate device. As can be seen in Appendix P, many of the features and performance specifications are identical. Note particularly that both systems contain a built-in air pump for automatic cuff inflation, have the same measurement accuracy for both blood pressure and pulse rate.

The principal differences are that the bar LCD to demonstrate mercury-column-like pressure flow is added to the new DM-3000 besides the segmental LCD to display pressure in a digital value as the predicate device and that optional function was added to switch the instrument to a pressure gauge with which inflation and deflation of the cuff is done automatically but the determination of blood pressure is made by a physician using a stethoscope. The setting of preset pressure and, for manual measurement, the setting of deflation rate, which the predicate device did not have, is also added to the subject device.

Because the difference between the subject device and the predicate device represent functional improvements that have been evaluated though both bench testing and clinical evaluation, it is clear that these changes raise no new questions with respect to either safety or effectiveness.

Testing conducted or standards applied to assure safety and effectiveness includes but is not limited to:

Clinical Performance and Accuracy: ANSI/AAMI Standard SP10-1992, Electronic or Automated Sphygmomanometers.

Electromagnetic Compatibility: IEC 60601-2, 2001 with test procedures according to IEC 61000-4-2, 2001; IEC 61000-4-3, 2001, IEC 61004-4, 2001 with Amendment 1, 2000 and Amendment 2, 2001; IEC 61004-6, 2001; IEC61004-4-8, 2001; IEC 61000-4-11, 2001.

Electromagnetic Interference: IEC 60601-1-2, 2001.

Description of the new device:

The Model DM-3000 Digital Blood Pressure Monitor is an automatic sphygmomanometer intended for measurement of systolic and diastolic blood pressures and pulse rate in adult patients under the supervision of a physician. Blood pressure is measured in the brachial artery using an arm cuff of the appropriate size. The unit includes air pumps for automatic cuff inflation, electric valves, button controls, circuitry to detect and process minute pressure oscillations, a bar LCD to display mercury-column-like pressure flow and a segment LCD to display blood pressure and pulse rate as a digital value and operation indications such as inflation, deflation, measurement error and battery error. Measurement can be made either automatically, where entire operation including inflation and deflation of the cuff and determination of blood pressures and pulse rate is automatically done, or

manually, where only inflation and deflation of the cuff are automatically done but determination of the blood pressures is done by a physician using a stethoscope. The unit saves the last reading in its memory circuit. The system is powered by the AC adaptor or the rechargeable nickel battery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2006

LDR Spine USA
% Mr. James W. Burrows
Director of Clinical Marketing
4030 West Braker Lane, Suite 360
Austin, Texas 78759

Re: K061017
Trade Name: Easyspine® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: July 19, 2006
Received: July 20, 2006

Dear Mr. Burrows:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director,
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix C Revision 6 July 2006

510(K) Number: K061086

Device Name : Model DM-3000 Digital Blood Pressure Monitor

Indications For Use :

The DM-3000 system is intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adolescents (age 12 to 21 years) adult patients, i.e., age 21 and above and is intended to be operated by physicians or under supervision of a physician.

Prescription Use____X____ AND / OR Over-The Counter Use _____

(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061086